



March 30, 2026

The Honorable Robert F. Kennedy, Jr., JD
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 20230

RE: CMS-1516-ANPRM-Medicare Program; Ensuring Safety Through Domestic Security with Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement in Medicare Participating Hospitals

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 22,000 nephrologists, scientists, and other kidney health professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on CMS-1516-ANPRM-Medicare Program; Ensuring Safety Through Domestic Security with Made in American Personal Protective Equipment (PPE) and Essential Medicine Procurement in Medicare Participating Hospitals Advance Notice of Proposed Rulemaking (ANPRM).

ASN appreciates the efforts of Centers for Medicare and Medicaid Services (CMS) to strengthen the resilience of the U.S. medical supply chain and to encourage domestic manufacturing of critical medical products. These efforts are especially important for the more than 560,000 Americans receiving maintenance dialysis. Dialysis is a life-sustaining treatment for people with kidney failure that requires consistent delivery of dialysis treatments to replace the kidney's functions.

Dialysis treatment requires continuous access to supplies and medications, such as hemodialysis dialysate, bloodlines, saline, heparin and other medications, and peritoneal dialysis solutions. The stockpiling of these products is not just dependent on the dialysis modality, but also on control guidelines and regulations. Even brief disruptions in manufacturing or distribution can immediately jeopardize patient care.

Dialysis supply chains are highly concentrated, with production of key products limited to a small number of manufacturers and facilities. As a result, disruptions at a single site can quickly lead to regional or national shortages. Recent events illustrate this risk. A production line closure in 2014 during a period of rapid growth in peritoneal dialysis use caused supply shortages and contributed to a drop in national home dialysis adoption rates. In 2024, production at a major

dialysis fluid manufacturer was disrupted by Hurricane Helene, forcing patients and providers to ration supplies, adopt suboptimal patient management strategies, and implement in cooperation with the FDA rapid importation of supplies from international sources to maintain patient care. More recently, shortages of hemodialysis bloodlines have posed significant challenges for providers and patients. These examples demonstrate that supply chain interruptions have had far-reaching effects on in-center home dialysis, and hospital care delivery, jeopardizing the administration's initiatives to expand home dialysis utilization and highlighting the need for policies that enable flexible responses and diversified supply sources.

ASN supports the agency's commitment to strengthening domestic manufacturing and enhancing the resilience of the U.S. medical supply chain, including efforts to expand capacity for PPE, essential medicines, and other critical medical products. ASN emphasizes that these efforts should be paired with policies that promote supply chain diversification, increased production volume, and broader geographic distribution of manufacturing to improve resilience and reduce vulnerability to disruptions at any single site.

For patients with kidney failure, uninterrupted access to dialysis supplies is a matter of survival, not convenience. ASN therefore urges consideration of dialysis supplies, including those used for both in-center and home treatment modalities, for inclusion in the Strategic National Stockpile as part of a comprehensive emergency preparedness strategy. ASN encourages CMS to take a coordinated approach that safeguards the continuity of dialysis care and ensures that supply disruptions, whether caused by natural disasters, manufacturing issues, or other unforeseen events, do not compromise patient health or access to life-sustaining therapies.

To discuss this letter further, please contact Lauren Ahearn, ASN Policy and Government Affairs Coordinator, at lahearn@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Sam M. Parikh". The signature is fluid and cursive, with a long horizontal stroke at the end.

Samir M. Parikh, MD, FASN
President